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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/090,185	03/04/2002	Xiaokui Zhang	600-1-253CON	5128	
23565	7590 12/15/2004		EXAMINER		
KLAUBER & JACKSON 411 HACKENSACK AVENUE			MCKELVEY, TERRY ALAN		
HACKENSACK AVENUE HACKENSACK, NJ 07601			ART UNIT	PAPER NUMBER	
	,		1636		
			DATE MAILED: 12/15/2004	DATE MAILED: 12/15/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/090,185	ZHANG ET AL.			
Office Action Summary	Examiner	Art Unit			
	Terry A. McKelvey	1636			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the o	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be tir within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	mely filed ys will be considered timely. Ithe mailing date of this communication. ED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 01 No	ovember 2004				
	action is non-final.				
3) Since this application is in condition for allowar	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims					
4) Claim(s) 1-82 is/are pending in the application. 4a) Of the above claim(s) 1-64,66,68-70 and 72 5) Claim(s) is/are allowed. 6) Claim(s) 65,67 and 71 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or	<u>2-82</u> is/are withdrawn from consid	deration.			
Application Papers					
9) The specification is objected to by the Examine		a hardha Faraninan			
10) The drawing(s) filed on <u>04 March 2002</u> is/are: a		*			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Applicati ity documents have been receive u (PCT Rule 17.2(a)).	ion No ed in this National Stage			
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summary				
<ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> <li>Paper No(s)/Mail Date 3/4/02.</li> </ul>	Paper No(s)/Mail Da 5) Notice of Informal F 6) Other: Seq Meno	ate Patent Application (PTO-152) Ce Comparison attachment			

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#### DETAILED ACTION

#### Election/Restrictions

Applicant's election with traverse of Group IV, species Stat3 (107-377) (SEQ ID NO:9), actually claims 65, 67, and 71 (not claims 65-67, 71, and 78-82 as indicated by Applicant) in the reply filed on 11/1/04 is acknowledged. The traversal is on the ground(s) that the groups designated by the Examiner fail to define compositions and methods with properties so distinct as to warrant separate examination and search. It is argued that a search for Stat protein fragments would result in the identification of subject matter related to methods of identifying modulators of said fragments, which falls within the scope of Groups II-III and VI, and thus there is no serious burden of searching and examining them together. This is not found persuasive because Groups II-III and VI are all classified separately from the elected invention of Group IV, which is prima facie evidence of burden because different class/subclasses are meant to be searched separately, in different applications, not together. In the instant case, a search of the Stat protein fragment of Group IV (in class 530, subclass 350), would not result in an adequate search of the assay methods of Groups II-III and VI, especially since many of

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the claims are not drawn to the specific fragments from Group IV. This is true for the non-patent literature search too. As explained in the last communication, a search for the specific method steps of Groups II-III and VI would not necessarily identify all of the relevant art for the other groups and thus it would constitute a serious burden to search these groups together, let alone with the additional search required for the elected Group IV.

Regarding the applicant's indication that claims 66 and 78-82 are included in the elected species of Stat3 (107-377) (SEQ ID NO:9), claim 66 is drawn to specific Stat3 mutants, which constitutes different species from the specific elected fragment of Stat3 (which is not a mutant sequence). Likewise, claims 78-82 are drawn to particular mutant sequences based upon the Stat protein fragments of claim 65, but which, because they are drawn to different sequences, are different species from the fragments of claim 65. Therefore, only claims 65, 67, and 71 are properly considered to be the claims drawn to the elected invention and elected species.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-64, 66, 68-70, and 72-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being

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drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/1/04.

## Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

In the instant case, the application is indicated as being a continuation of the parent application 09/387,418 in the transmittal papers, but the specification was not amended to place the claim for priority into the first sentence as required.

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## Specification

The disclosure is objected to because of the following informalities: the brief description for Figure 4A lacks the required sequence identifiers.

Appropriate correction is required.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 65, 67, and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Darnell et al (WO 96/20954) (Applicant reference AL).

Darnell et al teach a Stat 3 protein fragment which comprises as 1-514 of Stat 3 fused to the carboxyl terminus of Stat 1 (page 48, lines 29-31). See the attached sequence comparison which shows 100% sequence identity with claimed SEQ ID NO:9. This fragment comprises residues 107-377 of Stat 3 (SEQ ID NO:9) and reads on the elected Stat protein fragment of claim 65 because claim 65 is drawn to "A stat protein fragment

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selected from the group consisting of ... residues 107-377 of Stat3 (SEQ ID NO:9) ... . " In the absence of the Patent Office recognized "closed" language, "consisting of", as it pertains to the residues of the fragment (not the "consisting of that is a part of the Markush group), the fragment is interpreted to be "open", which means that Stat protein fragments that comprise residues 107-377 of Stat3 (SEQ ID NO:9) read on the claimed Stat protein fragment. These residues are within the Stat3 fragment taught by Darnell et al (along with additional aa residues on both sides), reading on the claimed and elected Stat protein fragment. The carboxyl terminus that is fused to the Stat 3 fragment reads on an epitope tag because the Stat 1 carboxyl terminus is large enough to constitute an epitope and thus this sequence can act as an epitope tag, such as for purification purposes using antibodies directed against that sequence. Additionally, the reference teaches that the chimeric Stat proteins (which includes the Stat protein fragment comprising aas 107-377) can be prepared by expressing the protein as a GST fusion (page 34). The Stat 3 protein fragment taught by Darnell et al also inherently interacts with c-Jun (105-334 aas) because it comprises aas 107-377 of Stat 3, as shown by the instant application, and thus the claim limitations of claim 71 are also met.

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#### Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem

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with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

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Page 9

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Jany a Milelen Terry A. McKelvey, Ph.D.

Primary Examiner Art Unit 1636

December 12, 2004

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Sequence Comparison

Sequence Comparison

ARR720822

ID ARR72082

ID A
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N-PSDB; AAQ89340.
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Receptor recognition factor implicated in transcriptional sugenes - useful in drug screening assays and/or for treating debilitations, derangements and/or dysfunctions, etc.

stimulation

of.

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                                                                                                                                                                                                                                                                STAT; STAT4; signal transducer and activator of transcription; DNA binding protein; ligand; receptor; oncogenesis; inflammation; autoimmune disease; antagonist; therapy.
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                                                                                                                                                                                                                                                                                                                                                                                             protein;
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"Claim 3, page 110"
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Mismatches (
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                                                                                                                                                                                                                                                                          Human; signal transducer and activator of transcription 3; ischaemia; immune response; Stat3; coronary atherosclerosis; vascular occlusion; hypoxia; stroke; angiogenesis; myocardial infarction; hypoglycaemia; inflammation; chronic obstructive pulmonary disease; cardiac arrest; insulin dependent diabetes mellitus; emphysema; trauma; scleroderma; shock; chronic active hepatitis; adult respiratory distress syndrome; nitrogen necrosis; proliferative angiopathy; autoimmune thyroiditis; sjogren's syndrome; multiple sclerosis; Addison's disease; epilepsy; polymyositis; rheumatoid arthritis; autoimmune infertility; anaemia;
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                                                                                                                                                                proliferative disease; Grave's disease; ulcerative colitis; sarcom carcinoma; degenerative disorder; gene therapy; growth deficiency; cirrhosis; hypoproliferative disorder; lesion; Statbeta.
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Pred. No. le-115;
; Mismatches 0;
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Location/Qualifiers

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                                                                                                                                                                                Matches
                                                                                                                                 Query Match
                                                                                                                                                                                                                                                                                                                                                                                                                                                                     hypoxic or ischaemic condition or disorder which is the result of stroke, ischaemia, coronary atherosclerosis, myocardial infarction, inflammation, tissue ischaemia in the lower extremities, infarction, trauma, vascular occlusion, prenatal or postnatal oxygen deprivation, suffocation, shock, chronic obstructive pulmonary disease, choking, asphyxia, hypoglycaemia, epilepsy, emphysema, adult respiratory distress syndrome, cardiac arrest, nitrogen necrosis, proliferative angiopathy e.g. diabetic microangiopathy with neovascularisation. Suppressing an immune response is useful for ameliorating a symptom of an autoimmune disease such as systemic lupus erythematosus, multiple sclerosis, insulin dependent diabetes mellitus, Sjogren's syndrome, scleroderma, polymyositis, chronic active hepatitis, mixed connective tissue disease, primary biliary cirrhosis, pernicious anatemia, autoimmune thyroiditis, idiopathic Addison's disease, vitiligo, anatemia, autoimmune thyroiditis, idiopathic Addison's disease, vitiligo,
                                                                                                                                                                                                                                                                                     gluten-sensitive enteropathy, autoimmune neutropenia, myasthenia gravis, idiopathic thrombocytopenia purpura, Grave's disease, Goodpasture's disease, rheumatoid arthritis, cirrhosis, pemphigus vulgaris, autoimmune infertility, bullous pemphigoid, discoid lupus, ulcerative colitis and dense deposit disease. The method is useful in preventing or treating specific proliferative and oncogenic disease which includes sarcomas and carcinomas e.g., bladder carcinoma, colon carcinoma, chronic leukaemia, fibrosarcoma, liposarcoma, degenerative disorders, growth deficiency, fibrosarcoma, liposarcoma, degenerative disorders, growth deficiency, fibrosarcoma, liposarcoma, degenerative disorders, growth deficiency,
                                                                                                                                                                                Sequence 720
                                                                                                                                                                                                                          method is also used
Stat3beta protein
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 response. Method involves administering to an individual a compound that modulate the activity of signal transducer and activator of transcription (signal). Modulating angiogenesis is useful for treating or preventing
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             The invention relates to a method of modulating angiogenesis and immune response. Method involves administering to an individual a compound that
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              treating a hypoxicompound that mode of transcription
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 Modulating angiogenesis and an immune response in an individual, treating a hypoxic or ischemic condition, comprises administering compound that modulates the activity of a signal transducer and
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                                                                                                                                                                                                                                                                      hypoproliferative disorders,
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                                                                                                              Similarity
RCLMEESRILQTAATAAQQGGQANHFTAAVVTEKQQMLEQHLQDVRKRVQDLEQKMKVVE
                                            RCLWEESRLLQTAATAAQQGGQANHPTAAVVTEKQQMLEQHLQDVRKRVQDLEQKMKVVE 60
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      Page 87-89; 94pp; English
                                                                                         Conservative
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SOUTH FLORIDA
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                                                                                                                                                                                                                                               in gene therapy. The present sequence
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                                                                                                            99.2%;
                                                                                                            Score 1377; DB 5; Pred. No. 9.1e-115;
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                                                                                                                                                                                                                                                 physical trauma, lesions and wounds.
heranv The present sequence is human
                                                                                           Mismatches
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   comprises administering signal transducer and a
                                                                                                                                 Length 720;
                                                                                         0;
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